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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,835	07/05/2000	HANS PROPPERT	HARMSEN002	8966

530 7590 10/30/2002

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/554,835	Applicant(s) Proppert
	Examiner Irene Marx	Art Unit 1651

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *Oct 21, 2002* .

2a) This action is **FINAL**. 2b) X This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *2-10* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) X Claim(s) *2-10* is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)	Notice of References Cited (PTO-892)	4.	Interview Summary (PTO-413) Paper No.s.
2)	Notice of Draftsperson's Patent Drawing Review (PTO-948)	5	Notice of Informal Patent Application (PTO-152)
3)	Information Disclosure Statement.s) (PTO-1449) Paper No.s)	6	Other:

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-21-02 has been entered.

Claims 2-10 are pending and considered on the merits.

Claim Rejections - 35 USC § 112

Claims 2-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 4 are vague and indefinite in the recitation "mediated by intestinal colonization of pathogenic fungi". It is unclear what is intended by "mediated by ...colonization" and how such diarrhea can be prevented in every instance. How is it determined which diarrhea is "prevented".

The claims are missing a critical element of the invention in failing the require the bacterial strain to be "living". See, e.g., specification, page 5.

Also the amount of *E. coli* administered is not claim designated in claims 2-10.

Claim Rejections - 35 USC § 102

Claims 2-5 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hockertz [AT] or Lodinova-Zadnikova et al. [AR] or under 35 U.S.C. 102 (a) as being clearly anticipated by DE 196 37 936 [AL].

The claims are directed to preventing or treating diarrhea mediated by pathogenic fungi in a mammal comprising administering *E. coli* DSM 6601.

This is a one step method.

The references are relied upon as explained below.

Hockertz disclose a one step administration of DSM 6601 (Nissle 1917) to mice. This administration would inherently prevent diarrhea in these animals and therefore anticipate the claimed method.

Lodinova-Zadnikova *et al.* disclose a one step administration of DSM 6601 to humans. This administration would inherently prevent fungi-mediated diarrhea.

DE 196 37 936 teaches the administration of DSM 6601 and nystatin to treat intestinal *Candida* infection (p. 12 of translation).

Response to Arguments

Applicant argues that Hockertz is directed to the administration of DSM 6601 to mice to enhance the immune response against fungal or bacterial infections. While, this is true, the same one step method of administering DSM 6601 would prevent fungi-mediated diarrhea. Thus, this reference, although silent about the mechanism of prevention of fungi-mediated diarrhea would inherently prevent such an infection since the mode of administration of DSM 6601 is the same. In like manner, Lodinova-Zadnikova *et al.* anticipates the claimed method.

With regard to DE 196 37 936, the document clearly teaches that the animal has an intestinal *Candida* infection and should be treated with NISSLE 1917 in addition to nystatin. Thus, this document teaches the administration of NISSLE 1917 (DSM 6601) to treat an intestinal fungal infection. Please note that applicant's claimed method is open to the administration of other drugs such as nystatin as taught in the prior art document.

"To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See id.; Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re* King, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Inherency is not

necessarily coterminous with the knowledge of those of ordinary skill in the art. See Titanium Metals, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See id. at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See id. at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . . , by one who has discovered its . . . useful properties."); Verdegaal Bros., 814 F.2d at 633.

This court's decision in Titanium Metals illustrates these principles. See Titanium Metals, 778 F.2d at 775. In Titanium Metals, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." Titanium Metals, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." Id. at 782. This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." See Atlas Powder Co. v. IRECO Inc. 51 USPQ2d 1943 (Fed. Cir. 1999).

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the "natural result" flowing from the reference's explicitly explicated limitations. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

In the instant case, the protection flows from the administration of DSM 6601. Thus applicants are incorrect in arguing that the anticipatory rejection is improper.

It is not relevant to the analysis of the claimed method that the reference makes no mention of (inhibiting, preventing etc.). Discovery of a new benefit for an old process does not render the old process patentable. In re Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Merely because the reference did not have one of applicant's purposes in mind when the (drug was administered) does not alter the drug's physiological activity. In the context of an anticipation rejection, the Federal Circuit stated, "Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results." Mehl/Biophile Int'l Corp. v. Milgraum, 192 F. 3d 1362, 1366, 52 USPQ2d 1303, 1307 (Fed. Cir. 1999).

See also *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) The board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A US patent to Dart disclosed inoculation using *P. cepacia* bacteria for protecting the plant from fungal disease. Dart was silent with regard to nematode inhibition, but the Board concluded that nematode inhibition was an inherent property of the bacteria, and therefore of the method as disclosed by Dart.

In short, whether or not the prior art practitioners realized all the consequences of their administration of the claim specific *E. coli* strain has little bearing on the patentability of an old method of administration. Applicants should look to their specification and amend the claims to either limit the subject of the method (one which suffers from intestinal colonization of pathogenic fungi), the mode of administration or the dosage or timing thereof, if the specification can be shown to support such limitations in order to move the prosecution forward.

It is noted also that the amount of *E. coli* to be administered is not claim designated. Also it is apparent that the bacteria are required to be viable to be effective in the touted process.

Applicants tout the antimycotic effects of the strain of interest. However, this is an inherent property of the strain. Moreover, antifungal activity is irrelevant in the "prevention" aspect of the claimed invention.